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(54) Abstract Title
Drug testing apparatus

(57) A test device is provided for testing for the presence of drugs within drinks, in particular drugs which are used in drug rape. The device may be in the form of a beer mat 54 which allows a user to dab a small amount of drink directly onto the beer mat, thus providing a quick indication of whether a drug is present in the drink. Preferably the device tests for benzodiazepines including Rohypnol and gamma hydroxy butyrate (GHB). The device may also test for other drugs such as ecstasy. The device comprises an antibody capable of binding the substance being tested for.

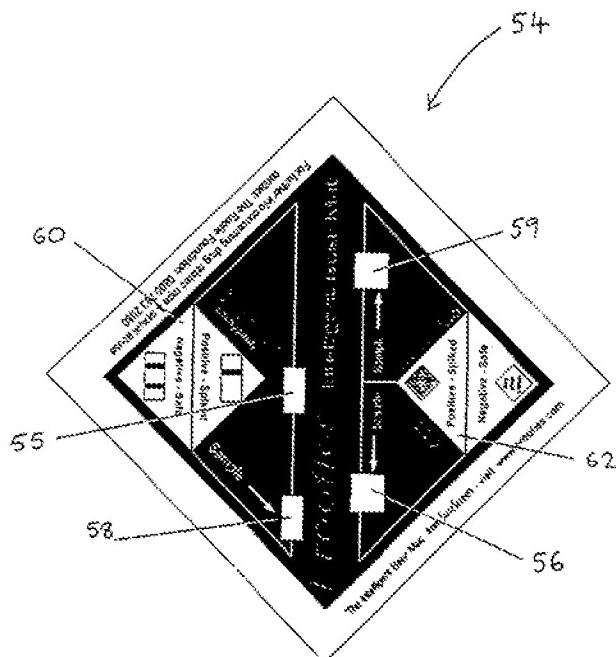


FIG. 7

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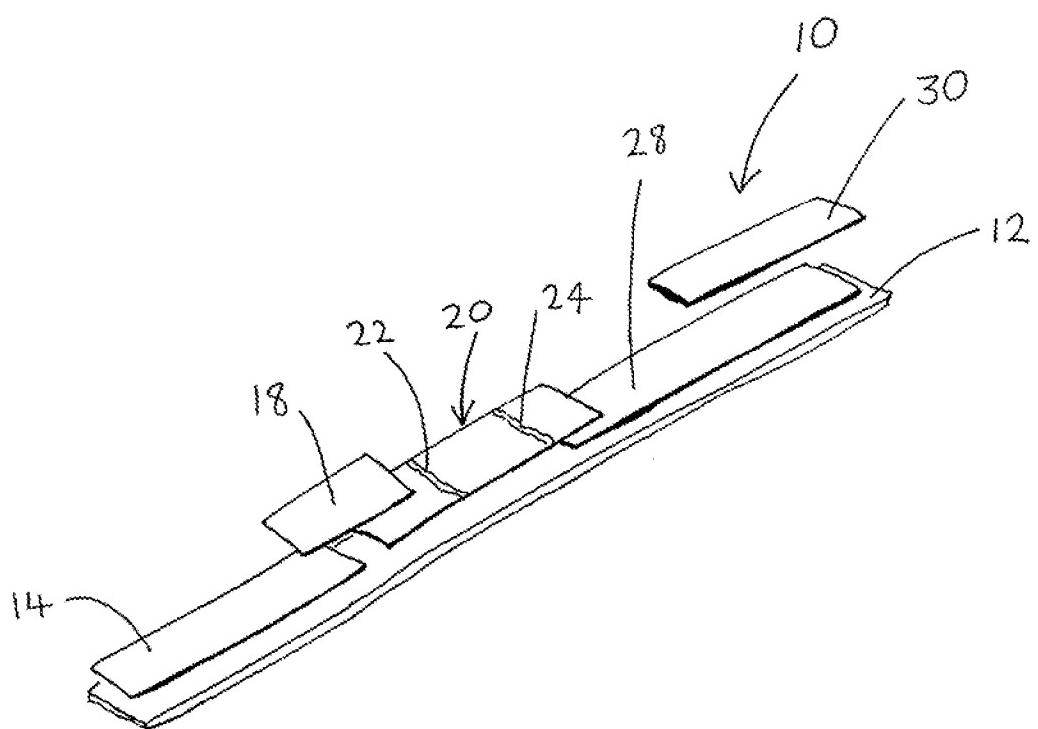


FIG 1

27

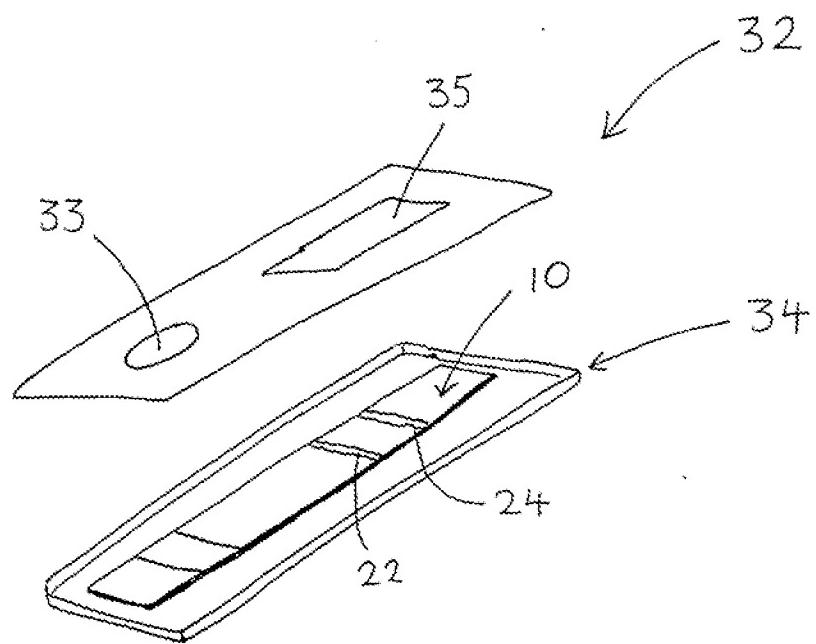


FIG 2

37

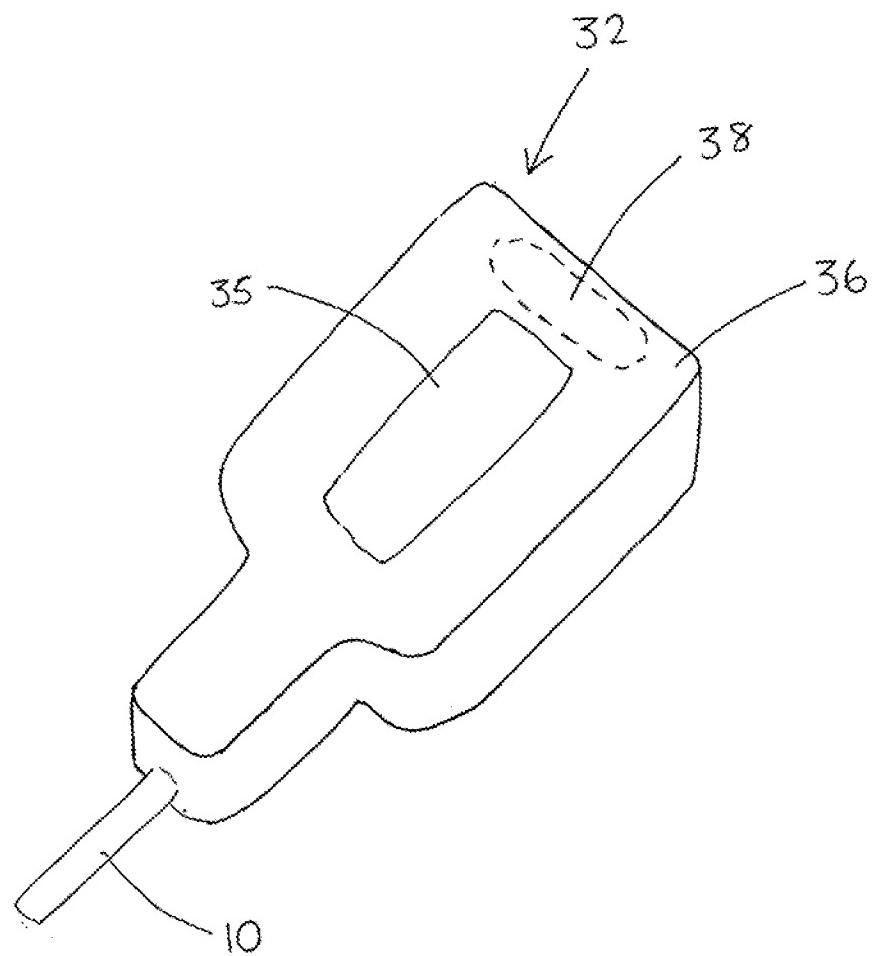


FIG 3

417

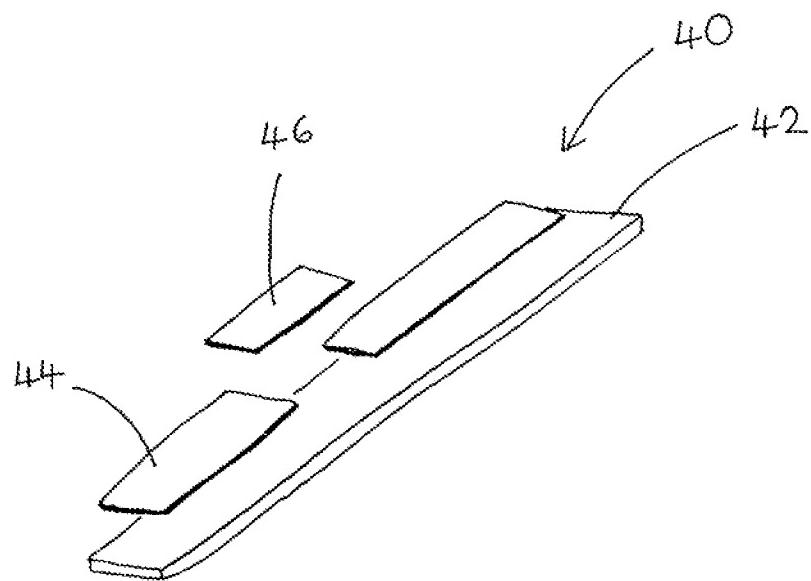


FIG 4

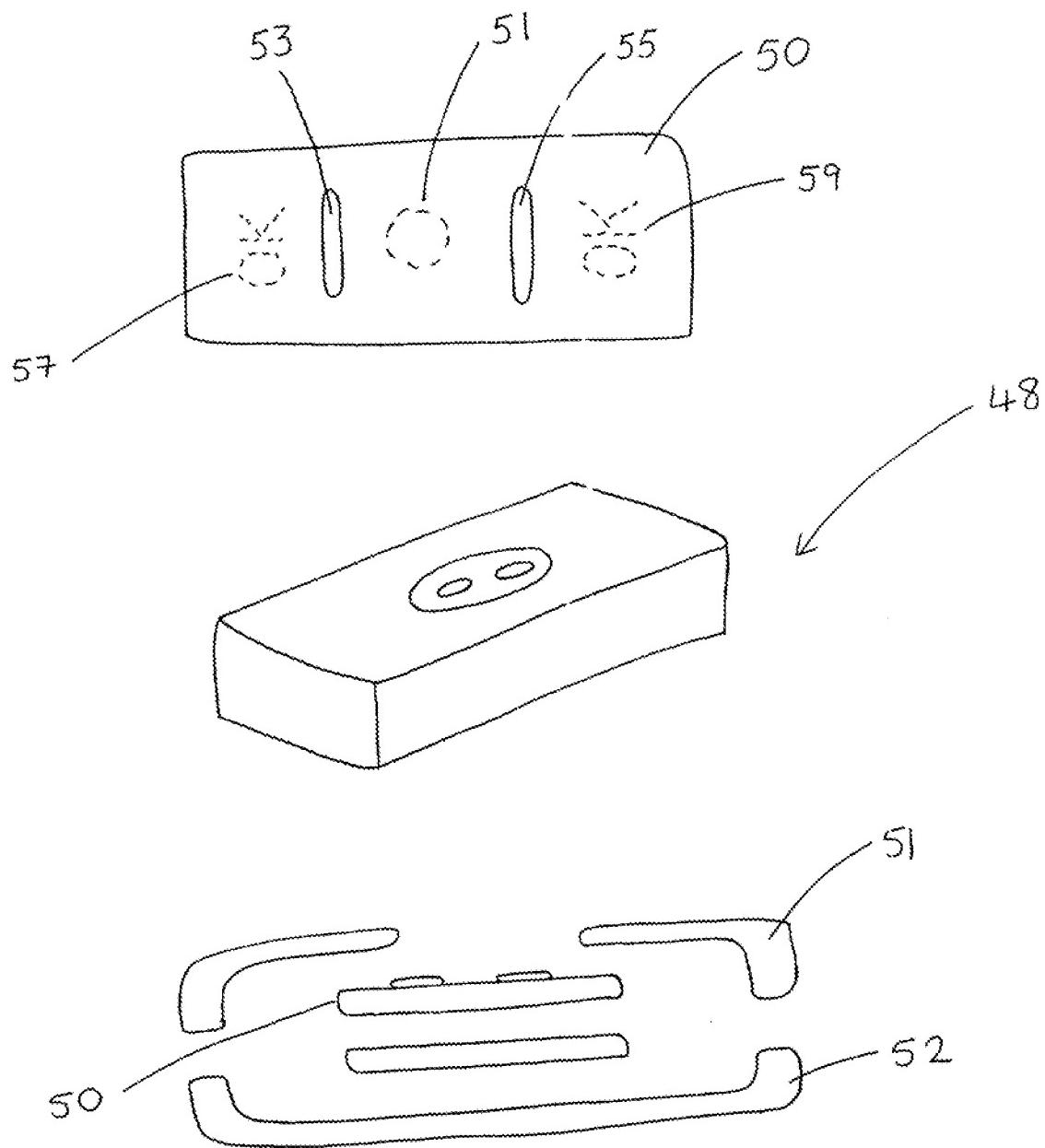


FIG 5

Negative Positive

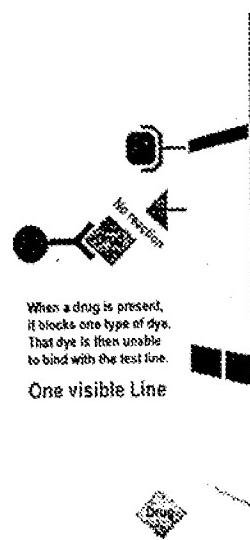
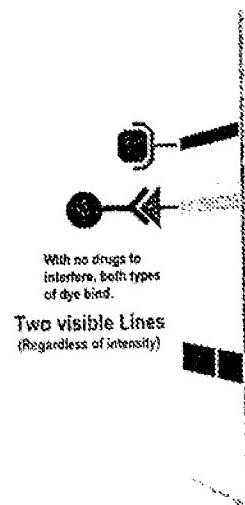
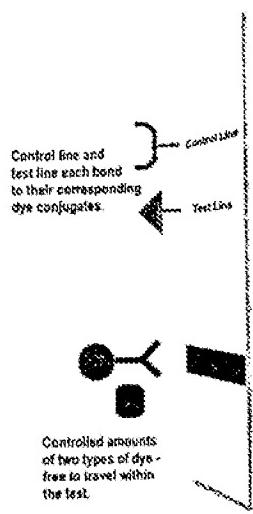


FIG 6A

FIG 6B

FIG 6C

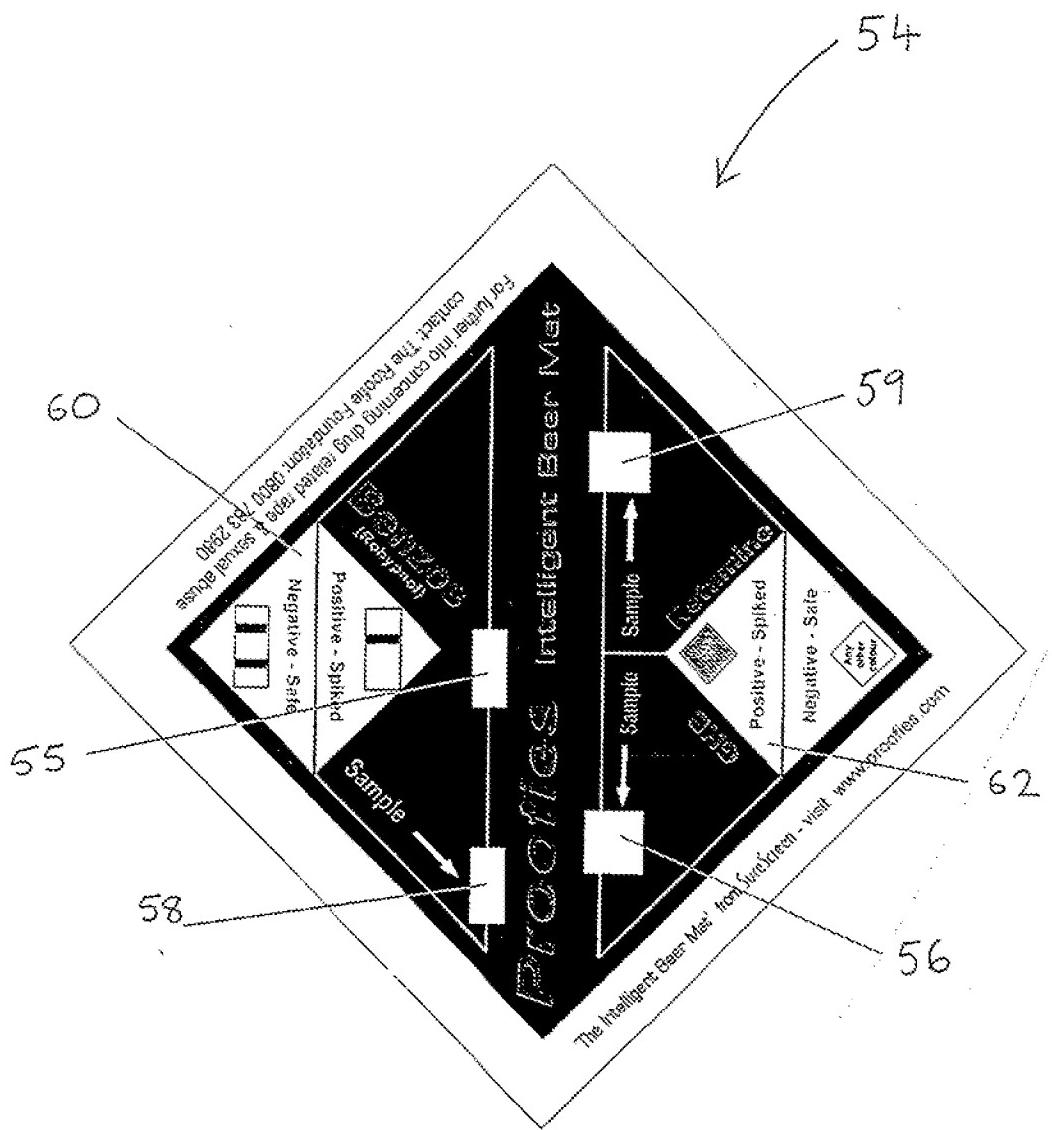


FIG 7

Drinks Testing Apparatus

The invention relates to a drinks testing apparatus for testing for the presence of substances administered covertly to drinks, particularly in social situations such as in bars.

The use of illicit drugs is widespread in society and consequently it is not difficult to obtain drugs and use them for purposes other than that for which they were originally intended, especially when this includes drugs such as prescription drugs, veterinary products and chemical and fabricated products manufactured for completely different purposes other than medical purposes.

There has been a tendency throughout history for substances to be deliberately administered to people without their knowledge with the deliberate intention of incapacitating them, altering their mood, or affecting their behaviour. This in particular has resulted in a recent trend of adding substances to drinks so that the recipient is incapacitated and in certain cases cannot remember the events following the administering of the substance. This has culminated in so called 'date rape' or 'drug rape' becoming a social problem.

For example, in 'drug rape' an unsuspecting woman has her drink 'spiked' with a substance, currently most commonly the drug 'Rohypnol' (flunitrazepam).

Other substances may also be used. When the woman does not suspect this and the substance added is not detected, drinks the substance and succumbs to the effects of the substance. During her incapacitated state the woman is exposed to sexual or other advances from the perpetrator or others, and the effects of the substance administered may conveniently prevent the woman from subsequently remembering the previous events.

In this example it is equally possible that the victim may be male, and of any age, or the substance may be administered in some other way, or in liquids

or solids or some other way of administering, or the substance may be administered in some remote manner with the intention of incapacitating the victim.

The assailant may not necessarily incapacitate the victim for the purposes of sexual assault. It is possible that robbery, or some other crime (such as making the victim sign documents, or reveal access codes to bank account) may take place while the victim is under the influence of the drug.

According to the invention there is provided a drinks testing apparatus as defined in any of the accompanying claims.

Embodiments of the invention will be described for the purpose of illustration only with reference to the accompanying drawings in which:

Fig. 1 is a diagrammatic exploded perspective view of a testing apparatus according to a first embodiment of the invention;

Fig. 2 is a diagrammatic exploded perspective view of a testing apparatus according to a second embodiment of the invention;

Fig. 3 is a diagrammatic perspective view of a testing apparatus according to a third embodiment of the invention;

Fig. 4 is a diagrammatic exploded perspective view of a testing apparatus according to a fourth embodiment of the invention;

Fig. 5 is a diagrammatic part perspective part sectional view of apparatus according to a fifth embodiment of the invention;

Figs. 6A to 6C are illustrations of the working of a test strip for use in the invention, using immunoassay techniques; and

Fig. 7 is a top view of a testing apparatus according to a sixth embodiment of the invention.

Referring to Fig. 1, there is illustrated a testing apparatus in the form of a test strip 10 which is designed to be dipped into a drink. The test strip includes a mounting member 12 which consists of an inert backing plastics material such as polyvinylchloride or polypropylene. The test strip 10 further includes a felt or fibreglass pad 14 which is bonded onto the mounting member 12. The pad 14 is capable of accepting a liquid by capillary action. The pad 14 is preferably impregnated with a surfactant or detergent designed to assist in the wetting and capillary action by reducing the surface tension of the drink into which the strip is dipped.

The test strip 10 further includes a second felt pad 18 soaked in a chemical agent consisting of gold conjugate and an antibody capable of detecting the substance being tested for.

The test strip 10 further includes a reaction membrane 20 located above the first and second felt pads 14, 18 when the strip is dipped into a drink. The reaction membrane 20 includes a line of a test antibody 22 which detects the antibody-gold conjugate complex.

Preferably the second felt pad 18 also includes a different antibody-gold conjugate, which acts as a quality control device in the test. In this case, the reaction membrane 20 includes a further line of a control antibody 24 which detects the control antibody-gold conjugate.

The test strip further includes an absorbent pad 28 which is able to collect the excess fluid as it travels up the test strip 10, and a covering 30 which protects the user's fingers from contacting the liquid and which may be printed with identifying details for the test.

Typical dimensions for the test strip 10 are 80mm long overall by 1mm

thick overall by 4mm wide, but these dimensions are not critical to the use and action of the device.

The test strip 10 is used as follows. The plain, un-printed end of the device (i.e. the end including the first felt pad 14) is dipped into the drink or into a small sample of the drink, or the drink may be dropped or poured onto this end of the test strip 10. Preferably the test strip 10 is labelled with the maximum level to which the strip may be dipped or the level beyond which liquid should not be dropped or poured onto the device. The drinks sample then travels up the strip by capillary action. At this stage, the test strip 10 may be removed from the drink but this is not critical.

When the drink sample does not contain a substance which is to be detected by the test, the liquid collects the antibody-gold conjugate and, when it reaches the area of the reaction membrane 20 which contains test antibody 22, binding takes place between the antibody-gold conjugate complex and the test antibody 22. Consequently, a coloured line forms to show that the test result is negative. This form of immunoassay test is often called a competitive immunoassay. If a quality control means is included, the control antibody-gold conjugate complex reacts with the control antibody 24 and a second "control line" forms to show that the constituents of the test are working correctly.

When the sample of drink being tested does contain a substance which is to be detected by the test, the liquid collects the antibody-gold conjugate as it travels along the strip 10 and the antibody-gold conjugate complex reacts with the substance to be detected, thus forming a substance-antibody-gold conjugate complex which is not then able to bind and react with the test antibody 22 on the membrane. Since no binding takes place there is no coloured line at the test position and this shows that the test is positive. If a quality control means is included, the control antibody-gold conjugate complex still reacts with the control antibody 24 and a second line or control line forms to show that the constituents of the test are working correctly. If at any time the control line or

area does not form this is an indication that the test device is not working correctly.

Figs. 6A to 6C illustrate the functioning of the immunoassay test in more detail. Fig. 6A illustrates the test strip 10 before dipping in the drink; Fig. 6B illustrates a negative result; and Fig. 6C illustrates a positive result.

The test strip 10 would commonly be used to test for benzodiazepines, in particular Rohypnol, which is the most common drug rape drug.

Referring to Fig. 2, there is illustrated a second embodiment of the invention. A test device 32 includes a test strip 10 substantially as described with reference to Fig. 1. In the Fig. 2 embodiment the test strip 10 is encapsulated in a housing 34 which is preferably of a plastics material such as high density polyethylene or polypropylene or some other inert substance. The sample of drink may be collected by a pipette or similar product designed to suck a small quantity of liquid which is then dispensed onto the test device 32 or onto a well 33 in the housing 34. The sample of drink is then drawn through the test device 32 by capillary action. The test strip 10 then performs in a similar manner to that described with reference to Fig. 1, with the results being visible through a viewing window 35.

Fig. 3 illustrates a third embodiment of the invention. In this embodiment, a test device 32 again incorporates a test strip 10 similar to that of the Fig. 1 embodiment. The test strip is held in a wand 36 which acts as a container for the test strip and a holder to allow the whole of the device to be placed into a drink. The wand 36 is preferably made from a plastics material such as high density PVC or polystyrene, and includes a viewing window 35. The wand 36 may also act as a stirrer to ensuring that the substance to be tested for is correctly disbursed throughout the drink before it is testing, in order that there is no risk of the substance remaining at the bottom of the glass. The wand 36 is also a convenient way to hold the device.

The wand 36 further includes a flexible portion 38 which when squeezed expels air from the device so that when the grip on the flexible portion is released, a suitable volume of drink enters the device and contacts the test strip before travelling up the strip by capillary action. The volume of liquid required is typically four to five drops, and this volume may be controlled by adjusting the area and displacement of the flexible area of the wand.

When the device 32 is used as a stirrer, the sealed wand 36 allows a small amount of liquid to pass into the device but, since air cannot pass out of the body of the wand 36, liquid is prevented from passing back out of the wand, hence there is no risk of antibody leaking out of the device.

Fig. 4 illustrates an alternative embodiment of the invention. In this embodiment, a test strip 40 is provided which is generally similar to the test strip 10 except that the reactive component is not immunoassay technology but analytical chemistry in so far as the reaction to detect the substance is a chemical reaction with an indicating substance. An example of its use is in testing for gamma hydroxy butyrate (GHB) which is an alternative substance used in drug rape. In this case, the reactive substance is an esteric reducing agent.

The test strip 40 is again designed to be dipped into a drink. It includes a mounting member 42 in the form on an inert backing plastic strip made of polyvinylchloride or polypropylene. A felt or fibreglass pad 44 is bonded onto the mounting member 42 and is capable of accepting a liquid by capillary action. As in the Fig. 1 embodiment the felt pad 44 may be impregnated with a surfactant or detergent designed to assist in the wetting and capillary action by reducing the surface tension of the drink into which the strip is dipped.

Above the felt pad 44 is a reaction membrane 46 which changes colour if the drug or substance to be detected is present in the sample. If the sample does not contain the drug or substance, the test does not change colour. Alternatively, for some drugs or substances, the test will not change colour if

the substance is present, and will change colour if the substance is not. An alternative to the membrane changing colour is a physical change or a change in the reflectance of the membrane under special lighting conditions such as ultra-violet light.

The above technology may also be substituted for the immunoassay technology in the embodiments of Figs. 2 and 3. Alternatively, the two different tests may be incorporated within a single test device.

A fifth embodiment of the invention is illustrated in Fig. 5. A test device 48 includes a test strip or similar device incorporating either immunoassay technology or chemical technology for the detection of substances as described previously, encapsulated within a semi-permeable membrane 50 such that liquid can pass through the membrane when required by action of priming the test. The membrane 50 and the test strip are housed within a plastics top 51 and bottom 52. The device 48 may be fitted to a container or disposable item such as a cup or glass, or the cap or base or other base of a bottle, carton or other container, so that drink is automatically drunk by the presence of the test device. In place of the semi-permeable membrane 50, there may be a cover or membrane which is peeled or punctured in order to admit fluid for the purpose of priming and carrying out the test.

The membrane 50 includes an area 51 for receiving a spot of the liquid to be tested, an area 53 containing a conjugate for benzodiazepines and an area 55 containing a conjugate for ecstasy. An area 57 contains an antibody for benzodiazepines and an area 59 containing an antibody for ecstasy. In the illustrated embodiment, a negative result produces an indication "OK".

The device 48 works in a similar manner to those described previously, with the liquid being conveyed along the membrane by capillary action, past the conjugate and the antibody for both benzodiazepines and ecstasy. The remainder of the membrane 50 acts as an absorbent area for the rest of the liquid.

Referring to Fig. 7, there is illustrated a further embodiment of the invention in the form of a drinks coaster or beer mat 54. The beer mat 54 consists of a planar sheet of cardboard or woodpulp material and has the general size and shape of a conventional beer mat. However, the beer mat includes surface markings which include a square representing a sample window 56 for testing for GHB and rectangles indicating a sample window 58 for testing for benzodiazepines (including Rohypnol), and a results window 55 for reading the results of the benzodiazepine test. The beer mat 54 further includes a marking in the form of a square representing a sample window 59 for testing for ketamine.

The sample window 58 (for benzodiazepines) includes a small piece of membrane attached to the beer mat 54. Onto the membrane has been placed a pad of gold conjugate which is magenta in colour, bound to an antibody having an affinity to the drug being tested. In the area of the results window 55 is a strip, line or other indication from another antibody which has an affinity for the antibody that is bound to the gold conjugate.

One or more drops of a drink placed at the start of the membrane will cause the liquid to travel along the membrane, carrying the antibody-gold conjugate complex with it as it travels. If the drug being tested for is present, it binds to this complex and blocks any binding sites on the complex. As the complex passes the second antibody, the gold conjugate, which is magenta in colour, does not bind and passes beyond the line, so the test does not show a colour change in the results window 55.

If there is no drug in the drink, the antibody-gold conjugate complex does not have its binding sites blocked and as it passes into the area of the results window 55 a second antibody binding takes place and the test is left with a coloured line. In this embodiment, there is no line when drug is present and a line when a drug is not present. Alternatively, the coloured line could instead be printed with the words PASS or OK or other suitable words to indicate that the drink is free from this particular classification of drug.

The benzodiazepines test is not limited to immunodiagnostic technology and may be performed in other ways such as colour change chemistry for example.

The GHB sample window 56 incorporates a small spot of a chemical indicator which may contain ferrous chloride in a buffer, this being oxidised to ferric chloride by the presence by GHB. When a spot of the drink is added to the GHB test area, there will be a colour change from the yellow or green ferrous chloride to a dark brown ferric chloride, if GHB is present in the sample.

The ketamine sample window 59 incorporates a similar suitable chemical test for ketamine.

The beer mat 54 may further incorporate a sample window for MDMA (methylene dioxy methamphetamine), known as ecstasy (not illustrated). The test for ecstasy may operate on immunodiagnostic principles. In one embodiment of the ecstasy test a small piece of membrane is attached to the coaster. Onto the membrane has been placed a pad of gold conjugate which is magenta in colour, bound to an antibody having an affinity to ecstasy, and on the membrane a stripe, line or other indication from another antibody has been added which has an affinity for the antibody that is bound to the gold conjugate.

One or more drops of the drink placed at the start of the membrane will cause the liquid to travel along the membrane, carrying the gold conjugate-antibody complex with it as it migrates. If ecstasy is present it will bind to this complex, and block any binding sites on the complex. As the complex passes the location of the second antibody, the gold conjugate, which is magenta in colour, does not bind and passes beyond the line, so the test does not show a colour change.

If there is no ecstasy in the drink, the gold conjugate-antibody complex does not have its binding sites blocked, and as it passes the stripe of second

antibody there is binding taking place and the test is left with a coloured line. In this embodiment there is no line when drug is present and a line when drug is not present. In another embodiment the coloured line is instead printed with the words 'pass' or 'ok' or other suitable word to indicate that the drink is free from this classification of drug.

The ecstasy test is not limited to immunodiagnostic technology and may be performed in other ways such as colour change chemistry for example.

The number and nature of the tests on the drinks coaster are not limited to the aforementioned, and tests may be applied to one side or both sides of the drinks coaster as appropriate.

In another embodiment the drinks coaster has a moisture detector region which changes colour if the drinks coaster is wet or if the test devices have been spoilt by moisture or usage, in which case the moisture indicator will serve as a quality check to ensure the tests are valid.

In the illustrated embodiment, alongside the sample windows 56, 58 and 59, are information areas 60 and 62 informing the user of the appearance of a negative and a positive test result.

Preferably the back of the beer mat gives instructions for use and may give other advice to those concerned about drug rape.

There is thus provided a convenient test for checking for the presence of substances (particularly drugs) added covertly to drinks.

In the prior art, there already exist many immunoassay tests suitable for detecting benzodiazepines in urine. The chemistry of the membrane, antibodies, conjugate, and enzymes are suitable for detecting this class of substances in urine because it is essentially a solution of salts which buffer the solution and maintain its pH to a value close to neutral.

Existing technology, when tested, failed to provide a reliable test in alcoholic drinks because the stability of the antibody was adversely affected by the acid present in cola drinks, fruit juice and cordials.

Existing technology also failed to provide a reliable test when the solution contained any significant level of alcohol.

It was necessary to ensure that the antibody and the antibody-gold conjugate complex used in this test was resistant to alcohol, fruit acids, flavours and additives such as preservatives and any other substances both natural and artificial which may be added or be a part of any drink to which this test may be applied. In part this may be effected by adding controlling substances to the strip such as, but not limited to, buffering chemicals such as phosphates or fluorides.

In the prior art, immunoassay tests are carried out in a clinical or a semi-clinical environment. This is partly because the test is used with urine, which may be a health hazard, and partly because the technology of the test is sensitive to moist conditions. The test is usually supplied in a sealed pouch protected with desiccant, and it is recommended that the test is only opened immediately prior to the test being carried out.

Realising that existing technology would not perform the task of detecting drugs in drink, the applicants carried out a series of exhaustive tests on antibody / conjugate chemistry to find an antibody that would withstand the aggressive conditions present in drinks, and in the environmental conditions likely to be encountered in a real testing situation.

The objectives for the product for detecting benzodiazepines were as follows.

The test must be capable of detecting all the commonly prescribed benzodiazepines, as well as the most commonly described drug used for drug

rape; namely Rohypnol.

The test must be sufficiently sensitive to detect the smallest hazardous dose of benzodiazepines in the greatest commonly purchased drink. The effects of Rohypnol are reported to be ten times greater than other benzodiazepines. Consideration also has to be taken into account that the antibody will have different detection limits with each of the common benzodiazepines. The applicants took a quantity equivalent to one tablet (with the minimum strength for that drug) of the benzodiazepine in one pint of liquid such as beer, as being the minimum detection level that is required. If a drink is spiked with less drug than this the effect is likely to be minimal.

The test must be accurate in as many drinks as possible. Since the most popular drinks at this time are alco-pops (alcoholic drinks containing a variety of fruit juices and alcohol) the test must be capable of detecting the least strength of tablet in these drinks.

The test should be easy to use.

The test should be rapid. A reaction time not exceeding two minutes is desirable.

The test should not be so sensitive to moisture that it will deteriorate out of its packet. The applicants set an arbitrary standard that the test should still work within 48 hours of it being out of its packet.

The test should be sufficiently robust that it should work when immersed in hot drinks such as coffee.

If the test is to be dipped into a drink, it should be so constructed that it will not leach out any of the chemical constituents into the drink. In particular, the antibody should not leach out into the drink otherwise the drink would be contaminated with murine antibody which could cause the person to develop

human anti-murine antibody. While this is not hazardous it could affect the performance of other immunoassay-based diagnostic tests .

It is preferable, in immunoassay test technology, to produce test strips that have a control line built into the test. If the control line develops, this shows that the test has worked. The control line has to be manufactured using a different antibody, often a goat antibody paired to a different conjugate. The robustness and quality of this control line must be at least as good as the test line used to detect the drug

The test should be available in discreet packaging, of a size that will fit in a handbag, pocket or purse.

By these various technologies the applicants challenged prepared murine and goat antibody/conjugate pairs with a wide range of drinks, treated or 'spiked' to different levels with prepared quantities of drug rape drugs, and found that monoclonal antibodies possessed the necessary accuracy in detection. Polyclonal antibodies were not used because it was discovered that they were in the main of fragile nature in the presence of alcohol.

Research was undertaken to identify other compounds present in common beverages that may affect the reliability of the test. Manufacturers of proprietary drinks supplied relevant information on the composition of their products. This identified the highest levels of substances that were available within the beverages.

From the above research a number of chemicals were identified that could have an adverse affect on the test results and reliability. These included(but were not limited to):

Salt (Sodium Chloride), Sugar (as sucrose, lactose, fructose, glucose), Aspartame, Maltodextrin, Benzoic Acid, Ascorbic Acid (Vitamin C), Oxalic Acid, Orthophosphoric Acid, Caffeine, Lipids, Citric Acid, Alcohol (as Ethanol), wide

range of fruit juices, thickening agents, preservatives, flavouring agents etc.

The tests according to the preferred embodiments of the invention overcome the various problems discussed above.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

CLAIMS

1. A drinks testing apparatus for testing for the presence of one or more substances administered covertly to a drink, the apparatus including:
 - sample receiving means for receiving a sample of the drink to be tested;
 - test means associated with the sample receiving means, for detecting the presence of the substance within the sample of drink; and
 - display means associated with the test means for displaying an indication of whether the substance was detected by the test means.
2. Apparatus according to claim 1, adapted for use in a public place, such as a bar.
3. Apparatus according to claim 1 or claim 2, the test means including: an area impregnated with an antibody-gold conjugate complex, the antibody being capable of binding with the substance being tested for; and a reaction membrane including an antibody which bonds to the antibody-gold conjugate complex, if the antibody-gold conjugate complex has not bonded with the substance being tested for, the binding on the reaction membrane resulting in a visible display.
4. Apparatus according to any preceding claim, wherein the antibody is a monoclonal antibody.
5. Apparatus according to claim 4, wherein the antibody is a murine antibody.
6. Apparatus according to any preceding claim, wherein the test means is capable of detecting the presence of benzodiazepines including Rohypnol within the drink.
7. Apparatus according to any preceding claim, the apparatus including test means for detecting the presence of a first substance or group of substances

and further test means for detecting the presence of a second, different substance or group of substances.

8. Apparatus according to claim 7, wherein the first substance/group of substances are benzodiazepines and the second substance is gamma hydroxy butyrate (GHB).

9. Apparatus according to claim 7 or claim 8, wherein the apparatus includes further test means for detecting the presence of methylene dioxy methamphetamine (ecstasy).

10. Apparatus according to any preceding claim, the apparatus being in the form of a drinks coaster.

11. Apparatus according to claim 10, wherein the drinks coaster comprises a generally planar mat of paper, cardboard or wood pulp material.

12. Apparatus according to claim 10 or claim 11, wherein the drinks coaster includes a plurality of sample receiving means, each sample receiving means being within an area defined on the surface of the drinks coaster, such that a sample of drink may be dabbed onto the area with a user's finger.

13. Apparatus according to claim 12, wherein each test means is associated with a particular sample receiving means and is provided within the area defined on the surface of the drinks coaster.

14. Apparatus according to claim 13, wherein the display means is also provided within the area defined on the surface of the drinks coaster.

15. A set of drinks coasters, the set incorporating one or more apparatus according to any of claims 10 to 14 and a plurality of further drinks coasters marked so as to appear identical with the apparatus according to any of claims 10 to 14, but excluding the test means.

16. Apparatus substantially as herein described with reference to any of Figs. 1 to 5 and Fig. 7 of the drawings.

17. Any novel subject matter or combination including novel subject matter disclosed herein, whether or not within the scope of or relating to the same invention as any of the preceding claims.



Application No: GB 0217339.1
Claims searched: 1-17

Examiner: Dr Jeremy Kaye
Date of search: 10 January 2003

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X, Y	X: 1, 2, 6-8 Y: 3-5, 7-17	US 6153147	(CRAIG) see whole document
X, Y	X: 1, 2, 6 Y: 3-5, 7-17	http://www.lifesignmed.com/drinkcheck_102000.htm , Jan 28 2001, "Status DrinkChek, Rapid test for Benzodiazepines in drinks"	
Y	3-5, 7-17	GB 2354320 A	(AMERICAN BIO MEDICA CORP.) p.4, 1.5 - p.6, 1.14
Y	3-5, 7-9	WO 00/05579 A1	(SYNTRON BIORESEARCH INC.) p.2, 1.2 - p.3, 1.22

Categories:

- | | |
|---|--|
| X Document indicating lack of novelty or inventive step | A Document indicating technological background and/or state of the art |
| Y Document indicating lack of inventive step if combined with one or more other documents of same category. | P Document published on or after the declared priority date but before the filing date of this invention. |
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Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^Y:

Worldwide search of patent documents classified in the following areas of the IPC^Z:

 G01N

The following online and other databases have been used in the preparation of this search report:

 EPODOC, WPI, PAJ, BIOSIS, CAPLUS, EMBASE, MEDLINE, SCISEARCH